

SPL ER/DL Team

Jan 19, 2011

Minutes

NEW Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Pat Cowall-Hanover

1. Meeting notices schedule for 2011
2. OTC Update from December meeting:
 - a. Is the import staff using the e-Listing database solely to confirm products have been drug listed or are they also still using the previous database for products that have not been required to be listed in electronic format (e.g., products for which no changes have occurred since last paper listing was submitted to the FDA)?
 - i. The import staff is instructed to use more than solely the e-List system. When a product arrives for importation, staff is advised to use the e-List database as well as to check the Drug Registration & Listing (DRL) database (i.e., legacy database) to determine if the listing submission has been received.
 - ii. Both the databases are electronic so it may be useful to clarify which database industry is speaking of when speaking to import staff products at the border.
 - b. What specific instructions or useful information can companies give to import agents who cannot locate drug listing information in the FDA database, even when the receipt for electronic submissions or copies of the paper submissions are provided? Is there a way for companies to direct the import agents to the appropriate information needed?
 - i. If there is a question of product listing, industry should provide a copy of the electronic submission to the agent and ask him/her to verify the product listing with both the SPL and Center contact. Products could be delayed/detained due to SPL listing issues or for other questions regarding compliance.
 - ii. Additionally, industry should contact the Division of Import Operations & Policy Regional Access Manager (RAM) to inform him/her that there is a problem and to advise that you are contacting SPL and/or Compliance about the matter. The RAM may be able to assist with resolving the problem/s.
 - iii. Contact the district office to identify the Regional Access Manager.
 - iv. Questions regarding validation should be directed to SPL/Data Standards Council while all compliance issues should be directed to the CDER Office of Compliance.
 - c. Discussion about when a manufacturer needs to drug list when the Private Label Distributor (PLD) already lists a drug and accurately identifies the Contract Manufacturer (CM), resulting in only one NDC number for the drug. Does this satisfy the reporting requirements for both the PLD and the CM?
 - i. There was a lot of discussion on this point. Pat is coordinating a teleconference with with Paul Loebach and others from FDA to continue discussions
 - ii. Lonnie: suggest that we also invite Veda Perkins (CBER) and Charisse Kasser (CVM).
 - iii. We encourage you to send questions.
3. Update from SPL indexing meeting
 - a. Productive meeting
 - b. There will be an indexing subgroup, led by Ed Millikan

- c. Attendees included several reps from data base companies
 - i. Clinical decision support – First Data Bank, etc.
 - ii. Pharma - GSK, Lilly, Merck
 - iii. Downstream users– Regenstrief, Epic
 - iv. Software Developers– Leander Fontaine and Gary Saner
 - v. FDA – 8 folks.
 - d. Work has potential to enhance patient safety. FDA needs to be clear about downstream uses when they create the indexing data.
 - e. Historically have looked at labeling for a product independently of everything else. In future, the data will be used in very different ways – data will be searched, filtered, conceptualized, compared, etc. Therefore need to be careful.
 - f. Order of approaching indexing the data: Box Warning, Pregnancy, Indications, ...
4. PCOL class is done. FDA still views this as being out for comment. There are plans to have a meeting to figure out when NLM is ready to receive them and display the data.
- a. FDA is ready and waiting for NLM to develop their functionality to use display the data for searching. FDA doesn't know the exact method.
 - b. Database developers had a preference to keep the information in tabular form.
 - c. Currently FDA plans to make it available in xml format, with NLM providing the display area.
5. Current labeling. Some SPL is still not current and in R4 on Daily Med.
- a. Per Lonnie, FDA did review SPLs that were over 1 year old, and contacted the companies.
 - i. Some companies complied. Some companies are out of business.
 - ii. Data is getting better. FDA will continue to do this to make sure that data is current.
 - iii. Approval letters now state that SPL should be submitted to eList within 14 days.
 - b. Issue: Some approval letters are still coming by snail mail instead of electronically.
 - i. Snail mail is getting more prevalent than in the past. Thus a big part of the 14 days is gone before industry gets the approval via snail mail.
 - ii. Request by pharma to FDA that approval letters should be sent electronically instead of by snail mail.
 - iii. This is new to FDA that pharma is not being notified promptly. Lonnie will take this back observation back to the review division.
 - c. What is the consequence of submitting the SPL late, ie beyond 14 days – outdated.
 - i. Suggest that if timeline can't be met, contact the FDA via letter of explanation – ie that SPL is in progress.
 - d. OGD does send approval letters by FAX or email. Still problem with new drugs.
6. Daily med still has R3 labeling for discontinued products. Process to remove is very laborious.....can we move toward something easier??
- a. Drug listing – NDCs can be removed by working directly with DRLS.
 - b. Can we get it off Daily Med– without having to create an R4 label, just to immediately have to remove it. (Company may not exist to get actually do the work.)
 - c. Per Lonnie....why this isn't an easy situation? Easy to make a mistake – remove the wrong file, etc. either FDA nor NLM want to be responsible for it.
 - d. Hints for delisting an old product that only has R3 SPL
 - i. If you are delisting a product...and you have both a market start and a market end date....
 - ii. COL is already available in R3.
 - iii. No manufacturing establishment data is needed. ie Company doesn't have to include the manufacturing sites and
 - iv. PDP images of carton and container label: put in a blank image saying that “no current image is available”
 - v. This is new information and good news.

7. Medguides are still not being identified on Daily Med because still in R3 format...and don't have correct LOINC codes.
 - a. Most of these are from before the validation procedures were implemented.
 - b. One thing that must happen is that Daily Med needs to have current—how do we identify and reach out to folks who are not doing things promptly.
 - c. Paperless labeling discussion – same discussion as above, and same issues. If current is not available in Daily Med....then can't move forward.
 - d. Lonnie receives a monthly report with a list of SPLs that don't have MedGuides coded correctly. Most are generic drug companies.
 - e. FDA will continue to contact them.
 - f. SPL is considered to be incomplete without the Medication Guide.
 - g. Repackers/relabelers download SPL to use for their SPL. And their SPL will be incorrect also.
8. Lonnie has been loading SPL manually if an establishment in the SPL has not yet sent in their DER electronically. FDA will probably not load these any longer because the establishment is now out of compliance. If you send a DL file and it includes an establishment that has not yet electronically drug listed, you are likely to get this error:

Greetings,

Drug establishments are required to be registered annually on or before December 31st. Content of labeling/listing SPL documents which, in the establishment data elements section, include information for drug establishments that are not registered electronically **may** no longer be manually loaded. Registrants of drug establishments have had from June 1, 2009, to December 31, 2010, to electronically register their drug establishments.

- Situation: validation errors relate to the operations that are included in the DL do not match the business operations included in the DER. Issue is that these operations are invisible to us in the DFARS site.
 - Suggest that sponsors contact the contract manufacturers to get them to correct their data. Several companies have made a lot of effort to reach out to their contract manufacturers.
 - Every indication is that Lonnie is getting out of doing manual overrides. Suggest that sponsors work with Lonnie on individual cases. Lonnie has been very good about helping to resolve these issues.
 - Suggestions:
 - o Asking for definitions of business operations
 - o Increase visibility of these business operations for CMs – these are included in the SPL and thus public information.
 - o Reasons for lack of visibility – concern about DUNS numbers being mixed and matched. Also DFARS site is pretty old.
9. Drugs for further processing: Howard reports that Pragmatic Lite validator now updated to check for this marketing category.
 10. NLM is changing the SPL: We were informed that FDA's process (receipt of SPL and/or posting to DM) can cause some changes to the file. When I submitted a subsequent SPL file for update, the FDA validates my 'new' file against the DailyMed file (which was changed by their process/system) and causes my 'new' file to fail...when I made no validatable changes from the last file I submitted. This is what I am being told by my vendor. I would like to know if others have experienced this problem. (Jean - Hospira)
 - a. Issue: Files submitted were different. File posted on Daily Med was different. Something changed in the processing:
 - i. Line breaks were added by either FDA or DailyMed.

- ii. Jean's vendor will be taken to Lonnie
 - iii. Let either Gary Saner or Keith Thomas or Terry Brunone know so that they can be aware.
 - b. What other issues have others had?
 - i. Searching on tradename?
 - ii. Validation issues with images. Needed to make minor change before file would be expected.
- 11. A new situation has been presented to us since the initiation of electronic listing and I'm looking for any advice for the best approach to List an product that is currently approved - has a USPI and product on the market - however, we're modifying the formulation to something that was approved a few years ago and never marketed. The source of this 'new' formulation is also different than the manufacturer of the formulation already in the market. We're looking to import the bulk tablets for testing next week and if everything goes as planned they'll proceed to our packaging location for release to the DC the first week of February. (Jackie Mohns-BMS).
 - a. Don't want a hold-up in customs.
 - b. This is a good use for the document type of "bulk ingredient" and marketing category of "Drug for further processing" – different NDC code. Then only need the bulk container shipping label. And you don't have to list the NDA or citation number. The "drug for further processing" will not go on Daily Med.
- 12. Training schedule out for FDA classes on SPL R4 for 2011.
 - a. Received several questions about whether these are comparable classes to those that have been given in the past....or updated.
 - b. Classes seem to be the same basic classes. Does anyone know????
 - c. Suggestion that add a class in how to manage data / coding for kits. Pat to contact Lonnie.